REMARKS

In the aforesaid Office Action, claims 33-36, 38 and 41 were rejected under 35 USC § 103(a) as being unpatentable over Trotta (U.S. Patent No. 5,620,649) in view of Charbrecek et al. (U.S. Patent No. 6,447,920), and claims 33-37 and 41 were rejected under 35 USC § 103(a) as being unpatentable over Zhong (U.S. Patent No. 6,048,620) in view of Charbrecek et al., and claim 39 was rejected under 35 USC §103(a) as being unpatentable over Trotta in view of Charbrecek et al. and Zhong, and claim 40 was rejected under 35 USC § 103(a) as being unpatentable over Trotta in view of Charbrecek et al. and Okuda et al. Claims 33-41 are pending.

The Examiner rejected claims 33-36, 38 and 41 under 35 USC § 103(a) as being unpatentable over Trotta in view of Charbrecek et al, stating that the first layers (10, 24) of Trotta correspond to the first and second layers of the claimed invention and the second layer (20) of Trotta corresponds to the covalently bonded functionality of the claimed invention, and that although Trotta does not teach that the second layer has a thickness of about 10 to 150 nm, Charbrecek et al. discloses coated biomedical devices having a bulk material coated with covalently bonded hydrophilic surface coating with a coating thickness that can be controlled to be from 0.001 micrometer (equivalent to 1 nanometer) to 100 micrometers, and that it would have been obvious to one of ordinary skill in the art to optimize the thickness of the second layer (the covalently bonded functionality of the claimed invention) taught by Trotta given that the thickness of the first layer can be controlled by controlling the amount of crosslinking agent present in the

solution and further given that Charbrecek et al. specifically teach that the coating thickness of a hydrophilic coating on a biomedical device can be controlled to obtain specific properties and the thickness can be controlled to be from 1 nm to 1,000,000 nm.

However, the 1 nm thick coating of Charbrecek is a hydrophilic coating which forms an outer-most surface of the device. In contrast, in Trotta, the three layers (10, 20, 24) are coextruded together, with the second layer (20) of Trotta being a central layer, providing a soft middle layer which bonds the inner and outer first layers (10, 24) of Trotta together. Thus, Trotta's second layer (20) is a coextruded layer, unlike the separately applied coating layer of Charbrecek et al., and the second layer (20) is a central layer located between an inner and outer layer, unlike the outer-most coating layer of Charbrecek et al., and the second layer (20) is a soft, functionalized tie-layer polymer which has a different nature and purpose than hydrophilic coating of Charbrecek. Consequently, there is no motivation to combine the references in such a way as to modify the second layer (20) of Trotta in view of Charbrecek et al. to provide the Applicant's plasma polymerized functionality covalently bonded to at least a section of a first surface of the first layer (the plasma polymerized functionality forming a film having a thickness of about 10 to about 150 nanometers, with a polymeric second layer bonded to the section of the first surface of the first layer).

The Examiner states that it would have been obvious to optimize the thickness of the second layer (the covalently bonded functionality of the claimed invention) taught by Trotta given that the thickness of the first layer can be controlled by controlling the amount of crosslinking agent present in the solution and further given that Charbrecek et

al. specifically teach that the coating thickness of a hydrophilic coating on a biomedical device can be controlled to obtain specific properties and the thickness can be controlled to be from 1 nm to 1,000,000 nm. However, the fact that the thickness of the second layer (20) of Trotta can be controlled and that the Charbrecek et al. coating is about 1 nm thick in no way provides the required motivation to modify Trotta to disclose the claimed invention, because the Charbrecek et al. coating is formed by a different process than the coextrusion disclosed in Trotta, and is used for a different purpose (hydrophilicity), and in a different location (as an outer-most layer) than the second layer (20) of Trotta. Moreover, Charbrecek teaches a potentially thin (1 nm thick) coating of a macromonomer which is polymerized to form an outer hydrophilic coating, while there is no teaching or suggestion that the coextruded layer of Trotta could be modified to be 1 nm thick and still be formed by coextrusion as required by Trotta, or still perform the function required by Trotta.

The Examiner rejected claims 33-37 and 41 under 35 USC § 103(a) as being unpatentable over Zhong in view of Charbrecek et al., stating that the balloon part of Zhong corresponds to the second layer of the claimed invention, the first coating of Zhong corresponds to the covalently bonded functionality of the claimed invention, the second coating of Zhong corresponds to the first layer of the claimed invention, and that although Zhong does not teach that their first coating has a thickness of about 10 to 150 nanometers, Charbrecek et al. discloses coated biomedical devices having a bulk material coated with covalently bonded hydrophilic surface coating with a coating thickness that can be controlled to be from 0.001 micrometer (equivalent to 1 nanometer) to 100

micrometers, and that it would have been obvious to one of ordinary skill in the art to optimize the thickness of the first coating (the covalently bonded functionality of the claimed invention) taught by Zhong given that the thickness of the first layer can be controlled by controlling the amount of crosslinking agent present in the solution and further given that Charbrecek et al. specifically teach that the coating thickness of a hydrophilic coating on a biomedical device can be controlled to obtain specific properties and the thickness can be controlled to be from 1 nm to 1,000,000 nm.

However, the 1 nm thick coating of Charbrecek is a hydrophilic coating which forms an outer-most surface of the device. In contrast, in Zhong, the first coating is a central layer, providing a bonding layer which bonds the second (outer-most) coating of Zhong to the balloon. Thus, there is no motivation to combine the references in such a way as to modify the first coating of Zhong in view of Charbrecek et al. to provide the Applicant's plasma polymerized functionality covalently bonded to at least a section of a first surface of the first layer (the plasma polymerized functionality forming a film having a thickness of about 10 to about 150 nanometers, with a polymeric second layer bonded to the section of the first surface of the first layer).

The Examiner rejected claim 39 under 35 USC § 103(a) as being unpatentable over Trotta in view of Charbrecek et al. and Zhong, and claim 40 under 35 USC § 103(a) as being unpatentable over Trotta in view of Charbrecek et al. and Okuda et al. However, as set forth above, the combination of Trotta in view of Charbrecek does not disclose or suggest a plasma polymerized functionality covalently bonded to at least a section of a first surface of the first layer (the plasma polymerized functionality forming a film having

a thickness of about 10 to about 150 nanometers, with a polymeric second layer bonded to the section of the first surface of the first layer).

In light of the above amendments and remarks, applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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